

REMARKS

Reconsideration of this application and the rejection of claims 1-12 and 14-15 are respectfully requested. Applicant has attempted to address every objection and ground for rejection in the Office Action dated February 8, 2008 (Paper No. 20080131) and believes the application is now in condition for allowance or in better form for appeal. The claims have been amended to more clearly describe the present invention.

I. Rejections Under 35 U.S.C. §112

Claims 1-12 and 14-15 stand rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement. The Examiner alleges that the claim language :“[t]he claims drawn to a rabbit skin wherein the skin processed by eluting and fractioning based on molecular weight” lacks support in the specification. Applicant submits that support for the claimed eluting and fractioning based on molecular weight can be found throughout the specification. For example, the process of the fractioning and eluting is described in the paragraph beginning on page 4, line 19 and includes distillation, which inherently separates by molecular weight. The process is further illustrated in Example 11.

In addition, Claims 1-12 were rejected in the Office Action as being vague and indefinite for reciting “a rabbit having rabbit skin.” Applicant has amended the claims to clarify the language of the claims and submit that the rejections have been overcome through

amendment. As such, Applicant respectfully requests that the rejections under 35 U.S.C. § 112 be removed and the application be allowed as presented.

## II. Rejections Under 35 U.S.C. §102

The Office Action maintained its rejections of Claims 1-12 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,057,324 to Shibayama et al. (“Shibayama”). Applicant respectfully submits that Shibayama is distinct from the presently claimed subject matter and is allowable in view of Shibayama. Applicant submits that the selection in the presently claimed subject matter provides more choices to vaccinate the rabbit skin to gain the active substance. According to Shibayama, the poxvirus was used to vaccinate rabbit, and in the experiments, the vaccinia virus was used. There is no clear designation of the strain of vaccinia virus and no difference between the strains in Shibayama.

Moreover, the presently claimed subject matter, as amended, recites among other things the use of a nitrogen atmosphere during the filtration and concentration steps to protect the active substance; which does not appear in Shibayama. Moreover, there is no indication in Shibayama that other strains could be used in a nitrogen environment.

The presently claimed subject matter, however, is based on extensive experimentation which showed differences among the quality and quantity of the resultant active substances when a different strain was inoculated. The strains of the presently

claimed subject matter, Claims 1-12, provide more choices to a person of ordinary skill in the art and are concentrated under a nitrogen atmosphere. The differences of the active substance attained from different species of rabbit when inoculated with vaccinia virus are recited in the present claims and described throughout the specification. Shibayama fails to disclose the same process, nor does Shibayama teach the resultant strains as disclosed in the presently submitted claims. There is no disclosure, teaching or suggestion in Shibayama to use a nitrogen atmosphere with other strains to achieve the presently claimed resultant active substance. Accordingly, the Section 102 rejection is respectfully traversed.

### III. Rejections Under 35 U.S.C. §103

Claims 1-12 and 14-15 stand rejected under 35 U.S.C. §103, as being obvious in view of Shibayama. The arguments asserted above traversing Shibayama are reasserted here. Applicant respectfully submits that the presently claimed subject matter is not rendered obvious in view of Shibayama. Regarding the product-by process type limitation, the difference between the process recited in Claim 1 and the process of Shibayama will result in the different products. For example, Shibayama utilized ultra-filtration to remove the portion of the substance of which the molecular weight was more than 20,000 and less than 1,000. In contrast, the method of Claim 1 uses a different filtration step under a nitrogen atmosphere which results in a difference in the quantity of the active substance. In addition, the presently claimed subject matter uses nitrogen to protect the active substance during the

filtration and concentration steps, which contributes in part, to the activity of the extracts. There is no teaching, suggestion or motivation in Shibayama to use a nitrogen atmosphere to protect the active substance and those skilled in the art would not be motivated to do so based on the teachings of Shibayama. The Examiner alleges that the skin must intrinsically exhibit the claimed SART activity, however, the quality and quantity of the resultant active substances are different, in part based on the protection of the active substance by nitrogen, and the reference cited provide no teaching, suggestion or motivation that the claimed SART activity would be resultant without using nitrogen.

Applicant has amended the claims and submits that the amended claims are allowable over the rejections set forth in the Office Action. As such, Applicant respectfully requests allowance of the claims and removal of all rejections.

#### IV. Conclusion

In view of the above-identified amendments and remarks, Applicant respectfully submits that the claims in their present form are allowable over the issues raised in the Office Action mailed February 8, 2008. In the alternative, the claims are submitted to be in better form for appeal. In the event that there are further issues which may be resolved

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by a telephone interview, the Examiner is urged to contact Applicant's undersigned Attorney  
at the telephone number listed below.

Respectfully submitted,

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